

FOOD AND DRUG ADMINISTRATION (FDA)

Joint Meeting of the Pulmonary-Allergy Drugs Advisory Committee, Drug Safety and Risk Management Advisory Committee, and the Pediatric Advisory Committee

Hilton Washington, DC/Rockville
1750 Rockville Pike, Rockville, MD

December 10-11, 2008

AGENDA

The committees will discuss the benefit risk assessment of long acting beta-2 adrenergic agonists for the treatment of asthma in adults and children.

December 10, 2008

8:30 a.m.	Call to Order	Acting Chair, PADAC
	Introduction of Committees	Co-Chair, PAC
	Conflict of Interest Statement	Kristine Khuc, Pharm.D. Designated Federal Official, PADAC
8:45 a.m.	Opening Remarks	
9:00 a.m.	Guest Speaker Presentation	
9:45 a.m.	FDA Presentation	
10:45 a.m.	Break	
11:00 a.m.	FDA Presentation	
11:45 a.m.	FDA Presentation	
12:15 p.m.	Lunch	
1:15 p.m.	FDA Presentation	
2:15 p.m.	FDA Presentation	
3:15 p.m.	Break	
3:30 p.m.	Sponsor Presentation	
3:45 p.m.	Sponsor Presentation	

4:20 p.m. Sponsor Presentation

4:55 p.m. Sponsor Presentation

5:30 p.m. Adjournment

December 11, 2008

8:30 a.m. Call to Order
Introduction of Committees

Conflict of Interest Statement

Acting Chair, PADAC
Co-Chair, PAC

Kristine Khuc, Pharm.D.
Designated Federal Official, PADA

8:45 a.m. Opening Remarks

9:00 a.m. Open Public Hearing

10:00 a.m. FDA Summary Remarks

10:30 a.m. Break

10:45 a.m. Questions/clarification
Committee Discussion

12:00 p.m. Lunch

1:00 p.m. Committee Discussion/Vote

4:00 p.m. Adjournment